DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamiaca, NY 11433

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 6, 2003

Bernhard Hampl, Ph.D.
Chief Executive Officer and President
Eon Labs, Inc.
227-15 N. Conduit Avenue
Laurelton, NY 11413

Ref: NYK-2003-13

Dear Dr. Hampl:

During an inspection of your drug manufacturing facility located in Laurelton, New York, conducted between the dates of December 5, 2002 and January 16, 2003, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). Such deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act as follows:

1. Failure to exercise strict control over labeling issued for use in drug product labeling. [21 CFR 211. 125(a)]. Bottles containing batch # 021159 Nabumetone 500mg Tablets, 100's were labeled Nabumetone 750 mg Tablets which resulted in a recall.

2. Failure to establish written procedures describing in sufficient detail the handling of labeling and packaging material. [21 CFR 211.122(a)]:

   a. There was no adequate written procedure for the operations of splicing rolls of labeling.

   b. There was no written procedure for the control of unused portions of roll labels which are returned to the label room.

3. Failure to establish written procedures designed to assure correct labels are used for drug products. [21 CFR 211.130]:

   a. There was no written procedure providing instructions for labeling personnel in the event of bar code scanner failures during the use of roll labels.

b. The written procedures, i.e., SOP QA-011, for drug product inspection during labeling operations did not specify frequency and sample size.

c. The written procedures for drug product inspection at the completion of finishing operations did not assure that the units examined for correct labeling are representative of the entire labeling run.

4. Failure to carefully examine labeling material issued for a batch for identity and conformity to labeling specified in the master or batch production records. [21 CFR 211.125(b)]. There are no records documenting adequate examination of spliced roll labels after roll splicing operations in the label room, such as, for labels used for Nabumetone Tablets lot # 021159.

5. Failure to provide assurance that containers and packages have the correct label by examination of packaged and labeled products during finishing operations. [21 CFR 211.134(a)]. Examinations during the labeling operations of lot 021159 Nabumetone 500 mg Tablets, failed to identify that bottles were labeled as Nabumetone 750 mg Tablets.

6. Failure to collect a representative sample of units at the completion of finishing operations for examination for correct labeling. [21 CFR 211.134 (b)]. Production records for Nabumetone 500 mg Tablets, batch # 021159 record labeling operations from 9:00 AM through 3:05 PM, but no label examinations of completed units were recorded after 1:55 PM.

7. Failure to conduct a thorough investigation of unexplained discrepancies or the failure of a batch or any of its components to meet any of its specifications. [21 CFR 211.192].

a. The investigation report into the mislabeling of lot 021159 Nabumetone 500 mg Tablets as Nabumetone 750 mg Tablets did not include any tracing, tracking, or reconciliation of label lots in an attempt to determine the number of mislabeled units, identify excess 500 mg labels and the source of the 750 mg labels that were incorrectly used.

b. The investigation report did not include any documentation of extending the investigation to other batches or products that may have been associated. For example, other products and batches that used label rolls that were spliced by Eon's label room were not identified and investigated.

8. Failure to have a written individual record of major equipment cleaning, maintenance, and usage. [21 CFR 211.182]. There were no equipment logs for the bar code scanner, programmed label reviewer and the roll label splicing equipment.

The above identification of violations and the observations on the form FDA-483 issued at the end of the inspection are not intended to be an all-inclusive list of violations. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. These actions include seizure and/or injunction.

We acknowledge receipt of Dr. Bhattacharyya's letter dated January 28, 2003 which responds to the Inspectional Observations. The response discusses corrective actions, and revision of procedures. That response letter may be referenced in your reply to this letter. We have the following specific comments concerning the response:

Procedure, QA-005, Post Finishing Examination of Labeled Material, should be clarified as to when examinations for correct labeling occur.

Since spliced roll labeling was implicated as a possible cause of the mislabeling, your investigation should be extended to all batches and products, within expiration date, that also were subject to roll labeling splicing operations.

Procedure, LP-026, Disposition of Excess Outserts and Roll Labels, should include some control procedure that assures labels returned to the label room are stored in the correct bin or storage location.

The violations above are indicative of a serious underlying problem(s) which resulted in product being distributed that was mislabeled. The implementation and effectiveness of promised corrections will be evaluated during a follow-up inspection.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. As part of your response to this letter please provide an update on the implementation of your promised corrections. If corrective action cannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to Compliance Branch, Food and Drug Administration, New York District, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,

Jerome G. Woyshner
District Director